

Notice of Allowability

Application No.

10/633,808

Applicant(s)

SOKOLOFF ET AL.

Examiner

Anand U. Desai, Ph.D.

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to October 10, 2005.
2. ☒ The allowed claim(s) is/are 1,3,5-11,13-17,20,21 and 27-30.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 10, 2005 has been entered.

Withdrawal of Rejections

2. The rejection of claims 1, 5-11, 13-17, 20, 21, and 27-30 under 35 U.S.C. 112, 2nd paragraph is withdrawn.
3. The rejection of claims 1, 5-11, 29, and 30 under 35 U.S.C. 112, 1st paragraph, as failing to comply with the written description is withdrawn based on examiner's amendment to the claims.
4. The rejection of claims 1, 5-11, 13, 16, 17, 20, 21, and 27-30 under 35 U.S.C. 112, 1st paragraph, enablement is withdrawn based on examiner's amendment to the claims.
5. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Studier et al. (Methods in Enzymology 185: 60-89 (1990)) is withdrawn based on examiner's amendment to the claims.
6. The rejection of claims 1 and 3 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sim, G-K. et al. (U.S. Patent 6,471,957 B1) in view of Lutz-Freyermuth, C. et al. (PNAS 87: 6393-6397 (1990)) is withdrawn based on examiner's amendment to the claims.

EXAMINER'S AMENDMENT

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Kirk Ekena on December 5, 2005.

The application has been amended as follows:

Examiner's Amendment to the Claims:

1. (Currently Amended) A composition for targeting hepatocytes comprising: a T7 ligand covalently attached to a compound, wherein,

a) said T7 ligand is selected from the group consisting of: ~~T7 phage, modified T7 phage,~~ T7 p17 protein, modified T7 p17 protein, ~~T7 p17 derived peptide,~~ T7 p17 rod domain, T7 p17 coiled coil domain, SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, ~~and a peptide or synthetic peptide analog derived from SEQ ID 1, SEQ ID 14, SEQ ID 15, SEQ ID 16, SEQ ID 17, SEQ ID 18, SEQ ID 19, SEQ ID 20, SEQ ID 21, SEQ ID 22, SEQ ID 23, or SEQ ID 24;~~ and[[,]]

b) said compound is selected from the group consisting of: drug, component of a drug or polynucleotide complex and polynucleotide.

29. (Currently Amended) A pharmaceutical preparation comprising: a compound selected from the group consisting of: drug, component of a drug or polynucleotide complex, and

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polynucleotide covalently attached to a T7 ligand selected from the group consisting of: ~~T7 phage, modified T7 phage,~~ T7 p17 protein, modified T7 p17 protein, T7 p17 rod domain, T7 p17 coiled coil domain, SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, ~~[[,]] and a peptide or synthetic peptide analog derived from SEQ ID 1, SEQ ID 14, SEQ ID 15, SEQ ID 16, SEQ ID 17, SEQ ID 18, SEQ ID 19, SEQ ID 20, SEQ ID 21, SEQ ID 22, SEQ ID 23, or SEQ ID 24.~~

30. (Currently Amended) A composition for targeting hepatocytes in vivo comprising: a T7 ligand covalently attached to a compound, wherein

a) said T7 ligand is selected from the group consisting of: ~~T7 phage, modified T7 phage,~~ T7 p17 protein, modified T7 p17 protein, T7 p17 rod domain, T7 p17 coiled coil domain, SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, ~~and a peptide or synthetic peptide analog derived from SEQ ID 1, SEQ ID 14, SEQ ID 15, SEQ ID 16, SEQ ID 17, SEQ ID 18, SEQ ID 19, SEQ ID 20, SEQ ID 21, SEQ ID 22, SEQ ID 23, or SEQ ID 24; and~~[[,]]

b) said compound is selected from the group consisting of: drug, component of a drug or polynucleotide complex and polynucleotide.

8. The following is an examiner's statement of reasons for allowance:

The prior art of record does not disclose the covalent conjugation of a compound with a T7 p17 tail fiber protein. The prior art of record shows the covalent conjugation of the first 11 amino acids of the gene 10 protein of T7 with a polypeptide sequence (cited in FINAL office

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action mailed 8/9/2005). Page 10 of the specification describes the enabled modified p17 proteins in Table 1a, which can be covalently conjugated to a complex that targets hepatocytes.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Allowable Subject Matter

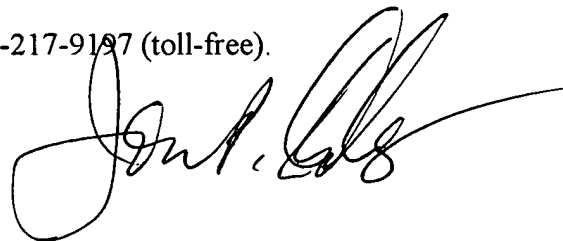
9. Claims 1, 3, 5-11, 13-17, 20, 21, and 27-30 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 5, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER